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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,547	09/04/2003	Robert Michael Roberts	UVMO:003USC1	5542

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,547

Applicant(s)

ROBERTS ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/7/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 182-196 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 182-196 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment and affidavit filed on 3/7/2005 has been received and entered into record and considered.

Currently, claims 182-196 are under examination.

Claim Rejections - 35 USC § 112

Written Description

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 182-196 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 182-196 are drawn to a method for detecting pregnancy in a bovine animal. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name' of the claimed

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subject matter sufficient to distinguish it from other materials.” Id. At 1567, 43 USPQ2d at 1405. The court also stated that

“[A] generic statement such as “vertebrate insulin cDNA” or “mammalian insulin cDNA” without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.” (emphasis added)

The court addressed the manner by which a genus of cDNAs might be described. “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that “the written description requirement can be met by ‘show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. “ Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

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The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product (emphasis added).

Thus, the instant specification may provide an adequate written description of the species, such as PAG4, 6, 7, 16, 17, 20, 21, per Lilly by structurally describing a representative number of PAGs that are capable of being an early pregnancy detector of bovine and become undetectable about 2 months post-partum, or by describing “structural features common to the members of the genus, which features constitute a substantial portion of the genus.” Alternatively, per Enzo, the specification can show that the claimed invention is complete “by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

In this case, the specification does not describe all the PAGs required to practice the method of claim 182 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any PAG, nor does the specification provide any physical or chemical characteristics of the other PAGs nor any functional characteristics coupled with a known or disclosed correlation between structure and function.

The specification describes only a few PAGs where structural diversities exist among the different PAGs. Therefore, it necessarily fails to describe a “representative number” of such species. In addition, the specification also does not describe “structural features common to the members of the genus, which features constitute a substantial portion of the genus.” As indicated by the case law that “[a] definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.” 43 USPQ2d at 1405. Thus, the specification does not provide an adequate written by merely reciting the function limitations of the PAGs, such as detectable in early pregnancy and undetectable at 2-month post-partum.

Scope of Enablement

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 182-196 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PAGs 4,6,7,16,17,20-21, does not reasonably provide enablement for any PAGs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The current invention recites the method of using PAG to detect early pregnancy in bovine. Applicant submitted affidavit provides support for certain PAG species, such as PAGs 4, 6, 16, 17 and 20. However, each PAGs possesses different chemical structure, i.e. amino acid sequence. As discussed before in this Office Action, the specification does not provide the complete structure of any PAG, nor does the specification provide any physical or chemical characteristics of the other PAGs, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Furthermore, the current invention does not have sufficient support for a "representative number" of the PAGs to constitute a full genus for all PAGs. Since one ordinary skill in the art would not be able to predict other PAGs in the functionality relates to the early pregnancy and post-partum, particularly due to the diversity of the chemical structures and compositions. Thus, the instant invention is limited to commensurate with the scope of the specific PAGs had shown concrete data in support of the recited method.

Response to Applicant's Arguments

Scope of enablement

In view of applicant's affidavits and arguments, first of all, applicant argues that according to MPEP §2464.01 (b), one only needs to show one working example to satisfy enablement requirement by the PTO Office (See Remarks, page 5, first paragraph). Second, applicant pointed out the preliminary data had shown that PAG presence is not limited to serum, but exists in other biological fluids such as saliva, milk and urine because one ordinary skill in the art would be able to identify and characterize the PAGs by simply following the procedure described from the specification and use routine immunological techniques (See Remarks, page 5-6; Dr. Green's affidavits). Applicant had shown that the above specific PAGs specifies exists in those samples, thus applicant had established enablement of the full scope of the invention by showing the presence of PAG in various sample types. Applicant's arguments have been considered but are not persuasive.

First of all, the issue here is not the enablement per se but the scope of enablement (emphasis added). Examiner considers the particular species of PAGs (except PAG-1) is capable of functioning the recited features. Nevertheless, the question rests in whether applicant is entitled to the full scope of the whole PAG genus. Presenting one working example as reasoned by applicant is not the legal standard for the scope of enablement, rather it is the standard of determining enablement per se.

Second, with respect to the routine immunological techniques in terms of isolating and characterization of the PAGs, the existing PAGs (4, 6, 7, 16, 17 or 20) cannot satisfy the full scope of enablement. Examiner pointed out in this Office Action that there exists chemical, structural diversity among these existing PAGs, and the limited number cannot fully represent the whole genus. It is well-known that alteration of amino acid would change protein function, the instant invention is entitled to the scope of the existing characterized PAGs, not all PAGs in the whole genus.

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Conclusion

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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May 23, 2005



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05/27/05